



Attorney Docket No. 401730/SKYE PHARMACEUTICALS, INC.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

AWADHESH K. MISHRA

Application No. 09/321,766

Art Unit: 1617

Filed: May 28, 1999

Examiner: E. J. Webman

For: THERMOPROTECTED
COMPOSITIONS AND PROCESS FOR
TERMINAL STEAM STERILIZATION
OF MICROPARTICLE
PREPARATIONS

RESPONSE

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated September 23, 2002, please enter the following amendments and consider the following remarks. Pages showing the requested changes are attached. This response is filed timely as it is accompanied by a Petition and a Fee for a three-month extension for filing a response under 37 CFR 1.136(a)

AMENDMENTS

IN THE CLAIMS:

Please cancel claims 47, 55, and 58-62 without prejudice and replace the indicated claims with:

21. (Twice Amended) An autoclavable composition of an aqueous injectable terminally steam sterilized suspension in a vial sealed under nitrogen atmosphere, said suspension containing particles of a water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μ m with not more than 3000 particles of 10 μ m or greater size and not more than 300 particles of 25 μ m or greater size, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent selected from the group consisting of trehalose,